

Drugs recently approved or pending approval

CUBICIN

The US Food and Drug Administration (FDA) has granted approval to Cubist Pharmaceutical Inc. (Lexington, MA) to market Cubicin (daptomycin for injection), the first in a new class of antibiotics called cyclic lipopeptide antibacterial agents. Cubicin is indicated for the treatment of complicated skin and skin structure infections caused by *Staphylococcus aureus* (including methicillin-resistant strains), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subspecies *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible strains only). Cubicin is not indicated for the treatment of pneumonia. Two randomized, multinational, multicenter, investigator-blinded studies compared the efficacy of Cubicin with either vancomycin or a semisynthetic penicillin. Adult patients (N = 1092) with clinically documented complicated skin and skin structure infections were enrolled; patients with bacteremia were excluded. Efficacy endpoints in both studies were clinical success rates in the intent-to-treat population (ITT) and clinically-evaluable (CE) population. In both trials, clinical success rates in the ITT population were 71.5% (382/534) in patients treated with Cubicin and 71.1% (397/558) in patients treated with comparator drugs. Clinical success rates in the CE population in both trials were 83.4% (372/446) for Cubicin-treated patients and 84.2% (384/456) for comparator drug-treated patients. The most common adverse effects associated with Cubicin included gastrointestinal disorders, injection site reactions, fever, headache, insomnia, dizziness, and rash.



INSPIRA

Pfizer, Inc. (New York, NY) was granted approval by the FDA to market Inspira (eplerenone tablets) to improve survival in stable patients with left ventricular systolic dysfunction (ejection fraction $\leq 40\%$) and clinical evidence of congestive heart failure (CHF) after an acute myocardial infarction (MI). Inspira is the first aldosterone receptor blocker to receive approval for this indication. Inspira was evaluated in a multinational, multicenter, double-blind, randomized, placebo-controlled study in patients clinically stable 3 to 14 days after an acute MI with left ventricular dysfunction and either diabetes or clinical evidence of CHF. Patients randomized to Inspira (n = 3319) were given an initial dose of 25 mg once daily and titrated to the target dose of 50 mg once daily after 4 weeks (if serum potassium was < 5.0 mEq/L). Dosage was reduced or suspended if serum potassium levels were ≥ 5.5 mEq/L. The risk of death in

patients treated with Inspira was reduced by 15% (hazard ratio, 0.85 [95% confidence interval, 0.75–0.96]; $P = .008$). Inspira is contraindicated in patients with serum potassium > 5.5 mEq/L at initiation, creatinine clearance ≤ 30 mL/min, and concomitant use with potent CYP3A4 inhibitors. The most common adverse effects associated with Inspira were hyperkalemia and increased creatinine levels. Inspira was previously approved for the treatment of hypertension.

OVIDREL

The FDA has granted approval to Serono, Inc. (Rockland, MA) to market Ovidrel (choriogonadotropin alfa injection) for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an assisted reproductive technology (ART) program. Ovidrel also is indicated for induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure. Ovidrel, a recombinant version of human chorionic gonadotropin (hCG), is the first liquid, ready-to-inject therapy for infertility treatment in the US. The safety and efficacy of Ovidrel was evaluated in 3 well-controlled studies: 2 studies for ART technologies and 1 study for ovulation induction (OI). The primary endpoint for the ART studies was the number of oocytes retrieved per patient. The primary endpoint in the OI study was patient ovulation rate. In all 3 studies, Ovidrel 250 μ g was found to be clinically and statistically equivalent to that of the approved urinary-derived hCG products. Ovidrel is contraindicated in women who exhibit prior hypersensitivity to hCG preparations, primary ovarian failure, uncontrolled thyroid or adrenal dysfunction, uncontrolled organic intracranial lesion, abnormal uterine bleeding of undetermined origin, ovarian cyst or enlargement of undetermined origin, sex hormone-dependent tumors, and pregnancy. Adverse effects associated with Ovidrel included injection site bruising, pain or inflammation, tiredness, nausea, headache, and abdominal pain.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Carbone, Hospital Physician, 125 Stafford Avenue, Suite 220, Wayne, PA 19087-3391.

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